



Pluristem Therapeutics Announces Publication in JCSM of Two-Year Follow-Up Data from Phase I/II Study in Muscle Regeneration and European Clearance for Ongoing Phase III Study

- ***PLX-PAD cells Demonstrated a Significant Increase in Muscle Volume and Strength***
- ***First Allogeneic Cell Therapy Study to Successfully Show the Potential of Treating Patients with Skeletal Muscle Injury***
- ***Ongoing Phase 3 Hip Fracture study in U.S. and Israel Cleared to Enroll Additional Patients in Denmark, Germany and the United Kingdom***

HAIFA, Israel, October 10, 2018 - [Pluristem Therapeutics Inc.](http://www.pluristem.com) (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative medicine company developing novel placenta-based cell therapy products, today announced that two-year follow-up data from its Phase I/II clinical study evaluating its allogeneic placenta-derived cell therapy product, PLX-PAD, for the treatment of muscle injury following hip replacement was published in the peer-reviewed *Journal of Cachexia, Sarcopenia and Muscle*.

Pluristem also announced that its ongoing Phase III study in the treatment of muscle injury following hip fracture, which is underway in the U.S. and Israel, has been cleared to enroll additional patients in Denmark, Germany and the United Kingdom. The study is being funded in part by an \$8.7 million grant from the European Horizon 2020 Program.

"Hip fracture surgeries often result in serious ongoing complications, including pain, disability, functional decline and even death, and there are currently no treatments approved for the post-operative regeneration of injured skeletal muscle," said Dr. Tobias Winkler, at the Berlin-Brandenburg Center for Regenerative Therapies, Julius Wolff Institute and Center for Musculoskeletal Surgery, and principal investigator of the Phase I/II and Phase III studies. "The published study is the first to successfully show the potential of an allogeneic cell therapy in treating patients with skeletal muscle injury, and we eagerly await data from the ongoing Phase III study as this promising therapy advances towards commercialization."

"The ongoing Phase III study has been precisely designed based on the results of the published Phase I/II study," added Dr. Winkler. "Based on our results of a reduction of postoperative stress by PLX-PAD, the indication has been adapted to hip fracture patients, who suffer even more due to the surgery-induced stress of hip arthroplasty. In addition, we included in the Phase III study endpoints which measure the systemic effect of PLX-PAD, which we observed in the earlier study, such as increase of contralateral gluteal muscle force and pro-regenerative immunological changes. Taken together, we believe the Phase III study design greatly supports the likelihood of its success."

The data published also supports PLX-PAD potential in treating additional muscle injuries. "The observations on postoperative stress reduction indicate that using PLX-PAD cells in cases where

perioperative stress is highly relevant, such as in sports injuries, traumatic muscle injuries, rotator cuff injuries and other surgical approach related injuries, in spine or knee surgeries, could lead to better outcomes in these patient groups”, states Dr. Winkler. “In addition, since hip fracture patients suffer widely from a condition of general muscle loss, called sarcopenia, leading to frailty and a reduction of mobility, we expect the data from the Phase III study to support the potential use of PLX-PAD in these patients as well. We believe that the Phase III study design will allow us to identify treatment parameters for both acute muscle injuries as well as general muscle loss.”

“The two-year follow-up data from our Phase I/II study demonstrate once again the safety and efficacy of PLX-PAD cell therapy product and further suggest that PLX-PAD is a highly versatile cell therapy with potential utility in multiple indications,” said Yaky Yanay, Co-CEO and president of Pluristem. “We continue to advance our Phase III programs and plan to open additional clinical sites in Europe to advance the recruitment of patients. The incidence of hip fracture is expected to increase markedly as the global population ages, and we believe PLX-PAD has the potential to significantly improve outcomes for patients in need of a novel treatment option following surgery.”

The Phase I/II study was a randomized, double blind, placebo controlled study conducted at the Charité Universitätsmedizin Berlin jointly with the Berlin- Brandenburg Center for Regenerative Therapies and the Julius Wolff Institute under the auspices of the Paul-Ehrlich Institute (PEI), Germany's health authority. The injured muscle studied was the gluteus medius muscle, which is intentionally cut during total hip arthroplasty. 20 patients were randomized into one of three cohorts: 150 million cell dose of PLX-PAD, 300 million cell dose of PLX-PAD or placebo. PLX-PAD or placebo was administered directly to the injured gluteus medius muscle during surgery. The primary efficacy endpoint was the change in the strength of the gluteus medius muscle six months after surgery. The key secondary endpoint was the change in the muscle volume of the gluteus medius six months after surgery, as measured by MRI. The results of the study showed that PLX-PAD demonstrated significant muscle regeneration including a highly significant improvement in muscle volume ($p=0.004$) and muscle force ($p=0.0067$) when observed six months after surgery compared to the control group.

A copy of the *Journal of Cachexia, Sarcopenia and Muscle* paper can be found [here](#).

About Hip Fracture

Femoral neck fracture is the most common form of hip fracture, with mortality rates of up to 36%, and annual treatment costs estimated to be between \$10-\$15 billion in the U.S. alone. Following surgery, many patients do not fully recover due to poor muscle regeneration, leading to significant morbidity, loss of the ability to live independently, and an overall decline in quality of life. The incidence of hip fracture is expected to increase as the population ages.

About Pluristem Therapeutics

Pluristem Therapeutics Inc. is a leading regenerative medicine company developing novel placenta-based cell therapy products. The Company has reported robust clinical study data in multiple indications for its patented PLX cells and is entering late stage studies in several indications. PLX cell products release a range of therapeutic proteins in response to inflammation, ischemia, muscle trauma, hematological disorders, and radiation damage. The cells are grown using the Company's proprietary three-dimensional expansion technology and can be administered to patients off-the-shelf, without tissue matching. Pluristem has a strong intellectual property position; Company-owned and operated, GMP-certified

manufacturing and research facilities; strategic relationships with major research institutions; and a seasoned management team.

Safe Harbor Statement

This press release contains express or implied forward-looking statements within the Private Securities Litigation Reform Act of 1995 and other U.S. Federal securities laws. For example, Pluristem is using forward-looking statements when it discusses its belief that its PLX-PAD therapy is advancing toward commercialization, its belief that the Phase III study design greatly supports the likelihood of success of the Phase III study, its belief that the published data supports PLX-PAD's potential in treating additional muscle injuries, its expectation that the data from the Phase III study will support the potential use of PLX-PAD in patients with sarcopenia, its plan to open additional clinical sites in Europe with respect to its Phase III programs and its belief that PLX-PAD has the potential to significantly improve outcomes for patients in need of a novel treatment option following surgery. These forward-looking statements and their implications are based on the current expectations of the management of Pluristem only, and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: changes in technology and market requirements; Pluristem may encounter delays or obstacles in launching and/or successfully completing its clinical studies; Pluristem's products may not be approved by regulatory agencies, Pluristem's technology may not be validated as it progresses further and its methods may not be accepted by the scientific community; Pluristem may be unable to retain or attract key employees whose knowledge is essential to the development of its products; unforeseen scientific difficulties may develop with Pluristem's process; Pluristem's products may wind up being more expensive than it anticipates; results in the laboratory may not translate to equally good results in real clinical settings; results of preclinical studies may not correlate with the results of human clinical studies; Pluristem's patents may not be sufficient; Pluristem's products may harm recipients; changes in legislation may adversely impact Pluristem; inability to timely develop and introduce new technologies, products and applications; loss of market share and pressure on pricing resulting from competition, which could cause the actual results or performance of Pluristem to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, Pluristem undertakes no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. For a more detailed description of the risks and uncertainties affecting Pluristem, reference is made to Pluristem's reports filed from time to time with the Securities and Exchange Commission.

Contact:

Efrat Kaduri
Head of Investor and Public Relations
972-74-7108600
efratk@pluristem.com

Karine Kleinhaus, MD, MPH
Divisional VP, North America

1-914-512-4109

karinek@pluristem.com